Though not required by the Examiner, Claims 4 and 8 are herein amended to remove possible ambiguity. After changing the dependency to Claim 3, the verifying step in Claim 3 provides the antecedent basis for "the verification" referenced in Claim 4. After removing "a verification out of the range of the predetermined data is detected" and substituting "said result of verification is out of range of the predetermined data," the step of providing a warning is clarified.

The Examiner rejected Claim 28 under 35 U.S.C. §112, second paragraph, as being indefinite with respect to the phrase "a predetermined carrier/a visual code." This is a typographical error. Applicant herein amends this claim to read "said predetermined carrier with a visual code." In view of these considerations and amendments, it is respectfully submitted that the rejection of Claim 28 under 35 U.S.C. §112 be withdrawn.

The Examiner rejected claims 1-11, 26, and 28 under 35 U.S.C. §103 as being obvious and unpatentable over U.S. Patent No. 4,943,949 to Hoover in view of U.S. Patent No. 5,672,170 to Cho et al. According to the Examiner, "Hoover discloses surgery using a surgical instrument accounting method (which uses bar codes, audio signals, and two sites)" and Cho "teaches the use of a syringe as a surgical instrument." Therefore, according to the Examiner, it would be obvious to use a syringe with the surgical instrument accounting method. However, despite the Examiner's comments, the Hoover patent does not mention bar codes at all.

Applicant respectfully traverses such rejection primarily because the cited references, alone or in combination, do not disclose "establishing first and second predetermined coded substance sites" nor disclose "a predetermined coded substance carrier" as recited in Claim 1. The Hoover reference relates to the combination of an instrument dispenser 10, a modified Mayo stand 135 and a computer 125. In Hoover, when instruments are removed from the dispenser a signal is transmitted to the computer and when an instrument is (later) placed on the Mayo stand, signals are transmitted to the computer to identify the instrument. There is an accounting of instruments according to Hoover when the identified instrument on the Mayo stand matches with a record of an instrument that was removed from the dispenser.

However, in Hoover, neither the locations on the dispenser 10 and the Mayo stand 135 nor the instruments are coded. There is no relationship between the location on the Mayo stand on which the instrument is placed and the instrument itself or the location in the dispenser from whence the instrument came. Hoover does not disclose "establishing a first predetermined coded site" or a second coded site as recited in Claim 1 because the instrument may be placed anywhere on the Mayo stand and need not be placed in a coded location. In addition, of course, Hoover does not disclose "a predetermined coded substance carrier" as recited in Claim 1.

The coding is significant because, among other things, when applied to the administration of drugs, it provides a visually striking monitor of drug administration throughout a procedure and at any time the practitioner can check at

a glace what has or has not been administered. Specification, page 9, lines 22-26. Further, the color coding may be used to indicate different classes of drugs thus helping to prevent dangerous combinations of drugs from different classes. Specification, page 6, lines 3-6.

The deficiency of Hoover is not resolved by Cho because Cho is directed to a surgical procedure not the use or monitoring of medical instruments. "Syringe" is mentioned only in passing in Cho, as stated in col. 1, lines 26-28, "generating the holes or channels within that heart wall by a syringe needle." This does not relate to the present invention or Hoover. Therefore, Claim 1 is not obvious over Hoover even in view of Cho.

Furthermore Applicant submits that the Examiner failed to show how Claims 2-11 and 28 are obvious over Hoover in view of Cho because he did not discuss the additional limitations recited in these claims. For example, these dependent claims include the steps of verifying use of the substance, recording the verification, monitoring movement of the carrier, and using a verification means to monitor movement of the carrier. Even Claims 11 and 28, which refer to bar codes are not anticipated or obvious in view of Hoover, because, as noted above the reference does not teach or suggest the use of bar code on the sites and/or instruments.

Finally, Applicant submits Claims 39 and 40 to be included in Group I for a method of monitoring substance administration. These claims do not introduce new

matter nor are they anticipated or obvious in view of the prior art since *inter alia* they depend on Claim 5 which is neither anticipated nor obvious. Claim 39 is supported in the specification on, for example, page 7, lines 27-33, which states that "the tray 1 design preferably incorporates separate sites or compartments 2 .... Each compartment 2 is the same coded colour 2c as the prefilled syringe S which that compartment 2 is intended to house." Thus the specification discloses that the first site and second site may be the same site, i.e., in the same compartment. In contrast, the first and second sites, i.e., the subcompartments 2a and 2b, as described on page 8, lines 4-11, may be different sites. The specification further supports "the step of monitoring said movement via verification means" of Claim 39 by stating on page 12, lines 3-5, that

> in an alternative form of the invention the compartments 2 are provided with suitable sensing or detection means 6, for example positioned in the base 7 of each subcompartment 2a/2b. Further, the syringes S are provided with identification means thereon in the form of magnetic/digital devices and others, which can be readily detected by the sensors 6 placed within the base of the tray 1.

Claim 40 is supported in the specification on, for example, page 6, lines 9-17, which states that "alternative coding can be incorporated including ... bar codes." The specification further states on page 10, lines 15-28, that "a conveniently arranged code positioned on the syringe S such as a bar code [may be] 'swiped' under a conveniently positioned reader as part of the drug administration routine [and] the detected code will be compared against the database information" thus identifying the

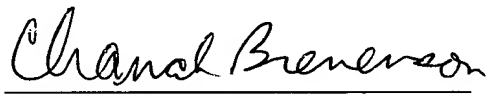
drug. "The information received by the monitoring apparatus will be conveyed and stored as a record." Specification, page 11, line 2.

Therefore, in view of the above amendments and remarks, Applicant respectfully requests that the application be reconsidered and that all pending claims be allowed.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

October 19, 2001



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alan Forbes MERRY

Serial No.: 09/508,499 Art Unit: 3738

Confirmation No.:

Filed: April 12, 2000 Examiner: T. Barrett

For: CODING OF SYRINGES TO MONITOR THEIR USE

MARKUP COPY OF AMENDED CLAIMS

4. A method as claimed in claim [1]3 including the step of recording the verification of the carrier at least during a use phase of said carrier.

8. A method as claimed in claim 1 including the step of comparing a result of verification of said carrier against predetermined data and including the step of providing a warning when [a] said result of verification is out of [the] range of the predetermined data [is detected].

28. A method as claimed in the one of the preceding claims 1 to 11 including the step of coding said first and second sites and [a] said predetermined [carrier/a] carrier with a visual code from one or a combination of the following:

i. a colour code

ii. a colour combination code

iii a pattern code

iv. a numeric code

v. an alpha code

vi. a bar code.

39. A method according to claim 5 wherein said first and second predetermined coded substance sites being the same site and including the step of monitoring said movement via a verification means adapted to detect the code on the carrier when said carrier is brought into a predetermined proximity with said verification means.

40. The method according to claim 39 wherein the verification means is a bar code scanner and the code is a bar code, said method also optionally including at least one of the following steps: (a) comparing the result of verification by said verification means against predetermined data; and (b) storing a record including the code or the result of verification.